K090410



# Premarket Notification 510(k) Summary
# CoolTouch Thermal Sensing Handpiece Accessory

This 510(K) Summary of safety and effectiveness for the CoolTouch Thermal Sensing Handpiece Accessory is submitted in accordance with the requirements of 21CFR 807.92.

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| Applicant: | New Star Lasers, Inc. dba CoolTouch, Inc. |
| Address: | 9085 Foothills Boulevard<br>Roseville, CA 95747 |
| | MAR 2 7 2009 |
| Contact Person: | Natalie R. Vollrath |
| Telephone: | (916) 677-1900 |
| Fax: | (916) 677-1901 |
| Preparation Date: | February 17, 2009 |
| Device Trade Name: | CoolTouch Thermal Sensing Handpiece Accessory |
| Common Name: | Handpiece Accessory |
| Classification Name: | Instrument, Surgical Powered, Laser 79-GEX |
| Legally Marketed Predicate Device: | New Star Temperature Diagnostic Accessory |
| Description of the CoolTouch Thermal Sensing Handpiece Accessory: | The Thermal Sensing Handpiece Accessory is a temperature detector which will provide the laser operator with a readout of the temperature of the treatment area |
| Intended use of the CoolTouch Thermal Sensing Handpiece Accessory: | For use as a sensing device to measure and display the temperature of the treatment area during procedures with the NS130 laser |
| Performance Data: | None |
| Conclusion: | Based on the evaluation of the risks and hazards and including various testing of the modifications, the CoolTouch Thermal Sensing Handpiece Accessory is substantially equivalent to the predicate device, the New Star Temperature Diagnostic Accessory |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

New Star Lasers, Inc.
% Ms. Natalie Vollrath
QA/RA Manager
9085 Foothills Boulevard
Roseville, California 95747

MAR 2 7 2009

Re: K090410
Trade/Device Name: CoolTouch Thermal Sensing Handpiece Accessory
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 19, 2009
Received: March 23, 2009

Dear Ms. Vollrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number**

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|---|---|
| **Device Name** | CoolTouch Thermal Sensing Handpiece Accessory |
| **Indications for Use** | The CoolTouch Thermal Sensing Handpiece Accessory is intended for use as a sensing device to measure and display the temperature of the treatment area during procedures with the NS-130 Laser. |

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM 3/27/2009

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

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